

60. The method of claim 59 wherein a transdermal patch containing the substance and the ionic salt in a concentration sufficient to create an ionic strength environment so that the substance migrates from the vehicle to the selected area of skin where hair growth is desired.

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**Remarks**

Applicant appreciates the Examiner's thorough examination of the subject application and requests reconsideration of the subject application based on the newly added claims 33-60 and the following remarks. Applicant acknowledges the request for the prior art statement. Applicant will review the art mentioned in the specification for relevancy and cite whatever reference is material to patentability in accordance with the Applicant's duty of disclosure. Applicant would also like to acknowledge the existence of three other related and pending applications, serial no.s 08/932,595, 08/936,188 and 08/936,189.

It is particularly apparent from the prior art cited by the Examiner that it is known that the introduction of nitric oxide into the body produces desirable effects, including penile erection, hair growth and increased circulation of blood flow to the surrounding area. Indeed, the art cited by the Examiner discloses these exact effects. It is also clear from the art cited by the Examiner that L-arginine, L-arginine salts and L-arginine derivatives are known to effectively release nitric oxide.

Specifically, the Examiner cites Saavedra et al. as disclosing a process for treating impotence in which a nitric oxide releasing material is incorporated into a

condom, the composition being in the form of liposomes or a patch which is applied topically. It also discloses that saline may be used. However, this reference does not disclose the creation of a hostile biophysical environment. In fact, the use of this biophysically hostile environment is what drives the nitric oxide precursor from the delivery vehicle into the surrounding skin. The mere use of saline will not achieve such a result. In fact, if L-arginine is mixed with a topical cream, nothing happens.

The Examiner also cites Garfield et al. as disclosing a process for healing wounds, treating impotence and restoring hair growth by topical application of an active ingredient. There is no mention of a hostile biophysical environment used in combination with a nitric oxide precursor such as L-arginine. Again, the use of L-arginine in combination with the hostile biophysical environment is novel and unobvious.

In fact, none of the prior art cited by the Examiner includes the use of a hostile biophysical environment. The present invention solely discloses that the use of such an environment encourages the L-arginine to preferentially migrate out of the delivery vehicle and into the surrounding skin. Thus, the present invention is based on the discovery that including a carrier with excess salt induces L-arginine to preferentially migrate from the vehicle to the skin to produce the desired effects.

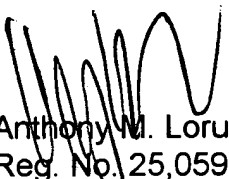
Accordingly, it is respectfully submitted that for the foregoing reasons, newly added claims 33-60 are patentable over the cited references, and, as such, claims 33-60 are allowable. It is also respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.



Applicants believe that no additional fees are required. However, if for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. 12-2147. If there is a problem with this submission, or the Examiner requires any further information, it is requested that the undersigned be contacted by collect telephone call.

Respectfully submitted,

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#### **CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.10**

I hereby certify that this document and any other documents referred to as being attached hereto are being deposited with the United States Postal Service on this date, 21 August 1998, in an envelope as "First Class" addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231



Shelby J. Walker